## REMARKS/ARGUMENTS

Claims 1, 3-6, 9-15, 17-21, and 24-26 remain in this application. Claims 1 and 20 have been amended without prejudice and claims 8, 22, and 23 have been cancelled without prejudice. Applicants reserve the right to pursue such amended or cancelled subject matter is subsequent continuation/divisional applications. Support for the amendments to claims 1 and 20 can be found throughout the specification and claims, e.g., claims 8 and 22. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

**Rejections Under 35 USC 103**

Claims 1-6, 8-15, and 17-26 were rejected under 35 USC 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) and Robinson et al (US 2003/0049316). See Pages 3-6 of the Office Action. According to the Office Action:

> "Ratnaraj et al. discloses a novel suspension system containing acetaminophen . . . .Singh et al. discloses a pharmaceutical suspension comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose . . . . Robinson et al. discloses tablets comprising NSAID and/or acetaminophen and wherein the particles are coated with a taste masking composition. The taste masking composition can comprise an insoluble film forming polymer (cellulose acetate or ethyl cellulose) and an enteric polymer (EUDRAGIT E-100). . . . It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Ratnaraj et al (a suspension of acetaminophen) in viw of Sing et al. (a suspension of NSAIDs) with Roninson et al. to arrive at the claimed invention. . . . One of ordinary skill would look to the coating compositions of Robinson et al. to coat the drugs of Ratnaraj et al or Singh et al. for the purpose of masking the taste of drugs."

See Pages 4-5 of the Office Action. Applicants respectfully disagree.

Independent claims 1 and 20 to recite dosage forms that comprise particles of an NSAID and/or acetaminophen that further comprise both an insoluble film forming polymer and an enteric polymer. Robinson et al. fails to disclose, or suggest, such particles comprising both an insoluble film forming polymer and an enteric polymer. Applicants wish to note that Eudragit E-100 is not an enteric polymer, but rather, as set forth in the attached information on the polymer from its supplier Evonik (Exhibit A), the polymer is soluble in gastric fluid and, accordingly, is not listed by Evonik as an "enteric coating" polymer.

Furthermore, in the interests of furthering this application to allowance, Applicants have additionally amended independent claims 1 and 20 to recite "wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1." As discussed above, as Robinson et al fails to disclose, or suggest, particles of an NSAID and/or acetaminophen that further comprise both an insoluble film forming polymer and an enteric polymer, it certainly also fails to disclose, or suggest, such a particle "wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1" as now recited in independent claims 1 and 20, from which the remaining claims depend.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

**Conclusion**

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5021/WEM.

Respectfully submitted,

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EUDRAGIT
Quick Starts
Enteric Coatings
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Protective Coatings
Melt Extrusion
Regulatory & Toxicology
Packaging & Delivery

## Protective Coatings

Many active ingredients require a protective coating to increase their stability and improve their mechanical properties. Protective EUDRAGIT® coatings dissolve in the acid medium of the stomach to rapidly release the active ingredient. They seal sensitive actives and increase patient compliance by masking tastes and odors. Even thin layers of EUDRAGIT® provide the desired effect, making it an extremely economical application. Pharma Polymers offer various cationic EUDRAGIT® E grades for protective coatings.

| Applications | EUDRAGIT® Grades | Availability | Functionality | Dissolution Properties | Monographs +DMFs |
|---|---|---|---|---|---|
| Taste masking, odor masking | EUDRAGIT® E 100 | Granules | Cationic polymer with dimethylaminoethyl methacrylate as a functional group | Soluble in gastric fluid up to pH 5.0 | Ph.Eur.,JPE,DMF 1242 |
| Insulating coatings | EUDRAGIT® E PO | Powder | | Swellable and permeable above pH 5.0 | Ph.Eur.,JPE,DMF 1242 |

**Application benefits of protectiveEUDRAGIT® coatings:**

- PH-dependent drug release
- Protection of sensitive actives
- Taste and odor masking
- Moisture protection
- Good storage stability
- Improved passage of the dosage form
- Smooth and glossy surfaces, good colorcoating



EXHIBIT A